



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,203	05/30/2001	Paul L. Hallenbeck	4-31452A	7861

1095            7590            01/27/2003

THOMAS HOXIE  
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

[REDACTED]  
EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
1648	11

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/870,203

**Applicant(s)**

HALLENBECK ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

### THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed

- after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 06 November 2002.

2b) This action is non-final.

2a) This action is FINAL.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1- 62 is/are pending in the application.

4a) Of the above claim(s) 8- 32 and 37- 62 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7, and 33- 36 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

This action is in response to communication of 10/31/02.

### ***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the groups represent a combination/subcombination. This is not found persuasive because the subcombination is not allowable. In the event that the product becomes allowable, claims for combination will be rejoined.

Claims 8- 32 and 37- 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1-7, and 33- 36.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 33- 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the intended meaning of

"contain" in the claims is. It is being treated in this office action as being open language (comprising).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

+33 over 34

Claims 1- 7 are rejected under 35 U.S.C. 102(b) as being anticipated by McClelland (US 5,543,328).

McLelland teaches a modified adenovirus fiber protein with a deletion between residues 400- 581 (Example 2 and claims 1 and 5).

The CD region of Ad5 is known in the art to be residues 441- 453 inclusive of the fiber protein. Mutation is defined in the specification as deletion or change (page5, lines 7-8).

Claims 1- 7 and 33- 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Wickham (US 6,455,314B1).

Wickham discloses a mutated subgroup C adenovirus fiber protein including CD region with reduced/ substantially eliminated binding to CAR, and other mutants comprising mutations/deletions in at least positions 441 and 442 of the fiber protein (examples 1- 10, and claims 1- 3, 6, 8).

Wickham does not refer to CD region of Ad5 but it is known in the art to be residues 441- 453 inclusive of the fiber protein. In claim 4 the term “contains at least” is interpreted to mean “comprising.”

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33- 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirby.

Kirby discloses Ad5 fiber proteins with mutations at residues 408 and 409 (Figure 5, pages 2811- 2812).

Kirby does not disclose a double mutant that contains both changes.

Art Unit: 1648

It would have been routine laboratory experimentation by one of ordinary skill in the art to examine combinations of known mutants to determine if combinations reduced binding/transduction of the CAR.

Thus, it would have been *prima facie* obvious to make a mutant fiber protein with residues 408 and 409 as taught by Kirby.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
January 22, 2003

  
JAMES C. HOUSEL 1/27/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600